

## REMARKS

Claims 1, 3 and 4 have been amended herein. Claims 5-20 and 23-30 are withdrawn. Subsequent to the entry of the present amendment, claims 1-4, 21 and 22 are pending and at issue. The amendment adds no new matter, as the claim language is fully supported by the specification and original claims.

### **I. Amendments to the Specification**

The abstract has been amended to remove the word “said” in compliance with MPEP § 608.01(b). Additionally, details regarding the pharmacokinetic properties which are improved by the invention were added to the abstract, as requested by the Office Action.

### **II. Rejection under 35 USC § 112**

Claims 1-4, 21 and 22 were rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing for failing to point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action states that Formula I recited in claim 1 is unclear due to the language “when.” Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution towards allowance, Applicants have amended claim 1 herein to remove the term and clarify the claimed invention.

The Office Action also alleged that the phrase “including mono-, di-, tri- and tetrasaccharides and larger” was unclear. Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution towards allowance, Applicants have amended claim 1 herein to remove the phrase and clarify the claimed invention.

The Office Action also alleged that the phrase “any hydroxyl...and silylation” is unclear. Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution towards allowance, Applicants have amended claim 1 herein to clarify the claimed invention.

The Office Action also alleged that the word “and” in claim 3 is unclear. Without acquiescing to the reasoning offered by the Office Action, in order to expedite

prosecution towards allowance. Applicants have amended claim 3 herein to clarify the claimed invention.

The Office Action also alleged that the phrases “particular sugar motif” and “specific amino acid residue” in claim 4 are indefinite. Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution towards allowance, Applicants have amended claim 4 herein to clarify the claimed invention.

Accordingly, Applicants respectfully request that the rejection under 35 USC § 112, second paragraph be withdrawn.

### **III. Claims not entitled to priority under 35 USC §119(e)**

Instant claims 1-4, 21 and 22 are not deemed to be entitled under 35 USC §119(e) to the benefit of the earlier priority date of provisional application 60/598,215 (hereinafter, “‘215”), 60/557,631 (hereinafter, “‘631”), or 60/516,838 (hereinafter, “‘838”), because the provisional applications allegedly do not disclose modification of hydroxyl, amino, or carboxyl functions by pegylation; do not disclose values of m equal to 2 or 3, and do not disclose values of n as high as 200. (Office Action, page 4).

Applicants respectfully disagree with Examiner. On page 17 of both the ‘215 and ‘838 applications, Applicants stated, “m is 1, 2, or 3 and n is any integer from about 1 to about 100, but may be greater.” On page 21 of the ‘613 application, it states that “n is any integer from 1 to about 100, but may be greater.” Applicants have expressly indicated that m can in fact be 2 or 3. In regards to “n,” Applicants also indicated that it was possible that “n” could be greater than 100.

Additionally, the provisional applications discuss modification of the hydroxyl, amino, or carboxyl functions. In particular, page 17 of the ‘823 application, page 18 of the ‘215 application, and page 22 of the ‘613 application reads, “sulfation, alkylation, acylation, deoxygenation, diazotization, silylation and the like.” This list describes methods in which a person skilled in the art could modify functional groups. Furthermore, a person skilled in the art would also know more ways exist to modify functional groups, hence Applicants “and the like.” One of skill in the art would know that pegylation is a process of covalent attachment of poly(ethylene glycol) polymer chains to another molecule.

Furthermore, Applicants would like to point out that the application contains the following language, "Methods and materials are described herein. However, methods and materials similar or equivalent to those described herein can be also used to obtain variations of the present invention. The materials, methods, and examples are illustrative only and not intended to be limiting." Applicants listed examples for disclosure purposes, and not to limit the Applicants only to those examples listed.

Accordingly, Applicants respectfully request that the objection under 35 USC §119(e) second paragraph be withdrawn, and the applicant be given the benefit of the provisional filing dates.

#### **IV. Rejection under 35 USC §102**

##### *Claimed invention*

The present invention is directed to a compound selected from the group consisting of compounds of Formula I and pharmaceutically acceptable salts, esters and prodrugs thereof. R<sub>1</sub> is any carbohydrate, which may contain one or more amino sugars, deoxy sugars or sialic acid sugars in any combination and which contains any hydroxyl, amino or carboxyl functions modified by, sulfation, alkylation, acylation, deoxygenation, diazotization, pegylation, or silylation. R<sub>2</sub> is the atom or group at the anomeric position of the carbohydrate R<sub>1</sub> and may be O, S, NH or CH<sub>2</sub>. R<sub>3</sub> is a linker comprising one or more alkyl, alkenyl, alkynyl, heteroalkyl, heteroalkenyl, heteroalkynyl, alkoxy, aryloxy, alkylthio, arylthio, aryl, heteroaryl, heteroarylalkyl, heteroarylthio, acyloxy, carboxyesters, carboxamido, arylalkyl, haloalkyl, haloalkenyl, haloalkynyl, haloalkoxy, cycloalkyl, acyl, alkylacylamino or acylamino groups or amino acid residues. R<sub>4</sub> and R<sub>5</sub>, are any natural amino acid or amino acid surrogate; m is 1, 2, or 3; and n is any integer from 1 to 200.

The claimed compound is a synthetic compound – it does not occur naturally in nature.

*Claims are not anticipated by Powell*

Claims 1-4, 21 and 22 are rejected under 35 USC §102 as allegedly anticipated by the Powell et al. article (hereinafter, "Powell"). Applicants respectfully traverse this rejection on the following grounds.

To anticipate a claim, the single prior art reference must disclose each and every element of the claim under consideration. *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983); MPEP §2131. There must be no difference between the reference disclosure and the claimed invention. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991). Furthermore, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Office Action alleges that "Powell teaches a peptide comprised of 17 amino acids which is glycosylated at its N-terminal Asn residue. In view of the similarity in structure between the peptide of the Powell article and Applicant's claimed compounds, inherently the peptide of the Powell article will have increased stability in the presence of peptides and proteases, increased thermal stability, increased dimmer half-life, increased bioavailability, and increased plasma half-life in comparison to a non-glycosylated analog, and inherently the carbohydrate will serve as a stable surrogate for a specific amino acid residue to the same extent claimed by Applicant." (Office Action, page 5.)

The present invention contains a non-naturally occurring compound. In particular, independent claim 1 contains a compound of Formula I where R<sub>1</sub> is any carbohydrate, which may contain one or more amino sugars, deoxy sugars or sialic acid sugars in any combination and which contains any hydroxyl, amino or carboxyl functions modified by, sulfation, alkylation, acylation, deoxygenation, diazotization, pegylation, or silylation. This modification of R<sub>1</sub> is not taught by Powell. The glycosylated peptide described in Powell adds a sugar to an amino acid within the peptide. The compound in Powell is not modified as described in claim 1, but rather is a naturally occurring carbohydrate motif.

Accordingly, Powell fails to anticipate the claimed invention because it does not disclose each and every element of the independent claim under consideration. Claims 2-4, 21 and 22 by definition contain all of the limitations of claim 1. Therefore, Applicant

respectfully submits that claims 2-4, 21 and 22 are patentable over the cited reference for the reasons given above with regard to independent claim 1 as well as because of the additional limitations contained therein.

Therefore, Applicant respectfully requests that this rejection be withdrawn.

*Claims are not anticipated by Danishefsky*

Claims 1-4, 21 and 22 are rejected under 35 USC §102(b) as allegedly anticipated by Danishefsky et al., U.S. Patent Application Publication, 2004/0102607, (hereinafter, "Danishefsky"). Applicants respectfully traverse this rejection on the following grounds.

As stated above, a single prior art reference must disclose each and every limitation of the subject claims, either expressly or inherently, to qualify as a prior anticipatory reference.

The Office Action alleges that Danishefsky teaches a pentapeptide at its N-terminal Ser residue, and that peptides are synthesized by reacting glycosylated serine with the remainder of the peptide.

The present invention contains a non-naturally occurring compound. In particular, independent claim 1 contains a compound of Formula I where R<sub>1</sub> is any carbohydrate, which may contain one or more amino sugars, deoxy sugars or sialic acid sugars in any combination and which contains any hydroxyl, amino or carboxyl functions modified by, sulfation, alkylation, acylation, deoxygenation, diazotization, pegylation, or silylation. This modification of R<sub>1</sub> is not taught by Danishefsky. The compound in Danishefsky is a glycosylated peptide which has carbohydrates attached to the amino acid residue within the peptide for inducing an immune reaction. The compound in Danishefsky is not modified as described in claim 1, but rather is a naturally occurring carbohydrate motif.

Accordingly, Danishefsky fails to anticipate the claimed invention because it does not disclose each and every element of the independent claim under consideration. Claims 2-4, 21 and 22 by definition contain all of the limitations of claim 1. Therefore, Applicant respectfully submits that claims 2-4, 21 and 22 are patentable over the cited reference for the reasons given above with regard to independent claim 1 as well as because of the additional limitations contained therein.

Therefore, Applicant respectfully requests that this rejection be withdrawn.

*Claims are not anticipated by Wagstaff*

Claims 1-4, 21 and 22 are rejected under 35 USC §102(b) as allegedly anticipated by Wagstaff et al., U.S. Patent No. 6,525,021 (hereinafter, "Wagstaff"). Applicants respectfully traverse this rejection on the following grounds.

As stated above, a single prior art reference must disclose each and every limitation of the subject claims, either expressly or inherently, to qualify as a prior anticipatory reference.

The Office Action alleges that Wagstaff teaches a "hexapeptide corresponding to the generic contulakin-G formula in which the first ten amino acids are deleted, and in which the N-terminal lysine residue has the structure set forth in Figure 1."

The present invention contains a non-naturally occurring compound. In particular, independent claim 1 contains a compound of Formula I where  $R_1$  is any carbohydrate, which may contain one or more amino sugars, deoxy sugars or sialic acid sugars in any combination and which contains any hydroxyl, amino or carboxyl functions modified by, sulfation, alkylation, acylation, deoxygenation, diazotization, pegylation, or silylation. This modification of  $R_1$  is not taught by Wagstaff. The compound in Wagstaff is a modification of a glycopeptides through removal of the de novo sugar. The compound in Wagstaff is not modified as described in claim 1, but rather is a naturally occurring carbohydrate motif.

Accordingly, Wagstaff fails to anticipate the claimed invention because it does not disclose each and every element of the independent claim under consideration. Claims 2-4, 21 and 22 by definition contain all of the limitations of claim 1. Therefore, Applicant respectfully submits that claims 2-4, 21 and 22 are patentable over the cited reference for the reasons given above with regard to independent claim 1 as well as because of the additional limitations contained therein.

Therefore, Applicant respectfully requests that this rejection be withdrawn.

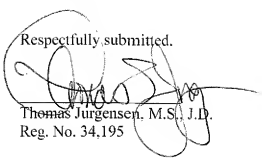
CONCLUSION

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested.

The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application. Fees for a one month extension of time are included with the filing of this paper. However, if additional fees are due, the Commissioner is authorized to charge any fees, or make any credits, to Deposit Account No. 502235 referencing the above-identified attorney docket number.

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Respectfully submitted,

  
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